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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/470,603	12/22/1999	DAVE BOVA	20720-103793	6359

7590 02/10/2004

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EXAMINER	
JOYNES, ROBERT M	
ART UNIT	**PAPER NUMBER**
1615	15

DATE MAILED: 02/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/470,603	Applicant(s) BOVA, DAVE	
	Examiner Robert M. Joynes	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 October 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Amendment, Response and Terminal Disclaimer filed on October 3, 2003.

Terminal Disclaimer

The terminal disclaimer filed on October 3, 2003 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6,080,428 B1 has been reviewed and is NOT accepted.

The application/patent which forms the basis for the double patenting rejection is not identified in the terminal disclaimer. While the Terminal Disclaimer filed disclaimed the terminal part of U.S. Patent No. 6,080,428 B1, the Disclaimer did not disclaim the terminal part of U.S. Patent No. 6,129,930 B1 which also formed the basis of the double patenting rejection. Therefore, the Disclaimer filed was not accepted.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,080,428. Although the conflicting claims are not identical, they are not patentably distinct from each other. U.S. Patent No. 6,080,428 claims a method of treating hyperlipidemia by administering an effective amount of nicotinic acid once per day in the evening or at night wherein said nicotinic acid is combined with at least one pharmaceutically acceptable carrier to form an oral dosage form wherein the dosage form causes minimal liver damage.

The instant claims recite a method of treating hyperlipidemia by administering an effective amount of nicotinic acid or *a compound metabolized to nicotinic acid by the body* once per day in the evening or at night wherein said nicotinic acid is combined with at least one pharmaceutically acceptable carrier to form an oral dosage form wherein the dosage form causes minimal liver damage. The difference in the instant claims being the inclusion of compounds that are metabolized to nicotinic acid by the body. U.S. Patent No. 6,080,428 further defines the terms "nicotinic acid" to include

specific compounds that are metabolized to nicotinic acid by the body (Col. 3, lines 30-41). Therefore, the claims of U.S. Patent No. 6,080,428 include all of the compounds recited in the Specification that can be metabolized to nicotinic acid by the body.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to treat hyperlipidemia with nicotinic acid or a compound that metabolizes to nicotinic acid in the body.

One of ordinary skill in the art would have been motivated to do this to achieve the same desired results with various compounds based on availability, price or efficacy of the individual compounds.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17, 34-132 of U.S. Patent No. 6,129,930. Although the conflicting claims are not identical, they are not patentably distinct from each other. U.S. Patent No. 6,129,930 claims a method of treating hyperlipidemia by administering an effective amount of nicotinic acid once per day in the evening or at night wherein said nicotinic acid is combined with at least one pharmaceutically acceptable carrier to form an oral dosage form wherein the dosage form causes minimal liver damage.

The instant claims recite a method of treating hyperlipidemia by administering an effective amount of nicotinic acid or *a compound metabolized to nicotinic acid by the body* once per day in the evening or at night wherein said nicotinic acid is combined

with at least one pharmaceutically acceptable carrier to form an oral dosage form wherein the dosage form causes minimal liver damage. The difference in the instant claims being the inclusion of compounds that are metabolized to nicotinic acid by the body. U.S. Patent No. 6,129,930 further defines the terms "nicotinic acid" to include specific compounds that are metabolized to nicotinic acid by the body (Col. 3, lines 49-57). Therefore, the claims of U.S. Patent No. 6,129,930 include all of the compounds recited in the Specification that can be metabolized to nicotinic acid by the body.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to treat hyperlipidemia with nicotinic acid or a compound that metabolizes to nicotinic acid in the body.

One of ordinary skill in the art would have been motivated to do this to achieve the same desired results with various compounds based on availability, price or efficacy of the individual compounds.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made

Response to Arguments

The Terminal Disclaimer filed is defective since it did not disclaim the terminal part of both U.S. Patents that form the basis of the double patenting rejection. Therefore, the double patenting rejections are maintained.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (571) 272-0597. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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